

REMARKS

The Examiner has rejected Claims 1 through 3 and 6 through 14. Claims 1 through 5 have been canceled by this amendment. Claims 6 through 14 are pending.

Rejections under 35 U.S.C. §102:

Claim 1 was rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Cheng U.S. Patent No. 2,922,420. Claim 1 was also rejected by Pyles U.S. Patent No. 5,669,882. Applicant has now canceled Claim 1. These rejections are, therefore, moot and no longer applicable.

Rejection under 35 U.S.C. §103:

Claims 6 through 14 stand rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over Krueger et al. U.S. Patent No. 6,478,751 in view of Pyles U.S. Patent No. 5,669,882. Applicant respectfully traverses this rejection for the following reasons.

The Examiner argues Krueger et al. disclose a bone biopsy system having many of the features claimed by Applicant, except for the “distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening and the proximal end of the device including viewable indicia indicating the position of the laterally oriented distal opening.” The Examiner relies upon Pyles for a teaching of a cannula tip with an arcuate curved surface and proximal viewable indicia. The Examiner concludes that one of ordinary skill in the art would have found the modification of the Krueger system incorporating the features of Pyles to allow rotation with decreased chance of tissue

damage and improved directional control to have been obvious. The Examiner likewise applies these references thusly against Applicant's method claims.

The Examiner's citation of the Krueger and Pyles references is premised on the erroneous view that one of ordinary skill in the bone biopsy field as would be the case with the Krueger reference, is the same as one of ordinary skill in the art in the spinal epidural anaesthesiology field. Put another way, the Examiner's rejection is based on the flawed notion that any and all medical devices, simply because they are medical devices similar in appearance, would be readily interchangeable in their respective features and functions.

Applicant's claimed *system*, and corresponding *method of obtaining a bone marrow sample*, are configured for a medical procedure whereby the cortex of the bone is penetrated and the biopsy aspiration device can be removably inserted into an outer cannula to obtain a bone marrow sample. There is no fair teaching or suggestion in Pyles to this effect - nor can one be fairly implied from a reference directed to a spinal epidural needle for use in anaesthetizing a patient via the central nervous system.

"Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure." In re Dow Chemical Co., 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). "Although the Commissioner suggests that [the structure in the primary prior art reference] could readily be modified to form the [claimed] invention, '[t]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.'" In re Laskowski, 871 F.2d 115, 10 U.S.P.Q.2d 1397 (Fed. Cir. 1989). Under the two step test for determining whether a prior art reference is nonanalogous and thus not relevant in

determining obviousness, it must be determined 1) whether the reference is “within the field of the inventor’s endeavor,” and 2) if not, whether the reference is “reasonably pertinent to the particular problem with which the inventor was involved.” In re Deminski, 796 F.2d 436, 230 U.S.P.Q.2d 313 (Fed. Cir. 1986).

With regard to the facts of the instant case, the inventor’s field of endeavor is bone marrow sampling, and the field of the Pyles reference is anaesthesiology. The particular problem to be solved by Applicant’s invention involves preservation of an aspirated marrow sample within bone. The Pyles needle infuses and directs medicaments, e.g., analgesics, in proximity to the central nervous system. In sum, Applicant’s claimed invention is a nonobvious improvement of the cited Krueger system. John Krueger developed the improvement of his own previous system based on problems encountered in the bone sampling field – and not from anesthesiologists.

One of ordinary skill in the art would not have combined the teachings of Krueger with those of Pyles, as Pyles is not in the same field of endeavor as Krueger and Pyles is not contemplative or suggestive of sample integrity concerns involved in Applicant’s technology. Furthermore, one would not have been motivated to combine the references as the claimed system, and cited Krueger system, require the presence of interactive componentry that is absent from Pyles. The Examiner has thus failed to present a combination of teachings that can adequately support a rejection on obviousness grounds.

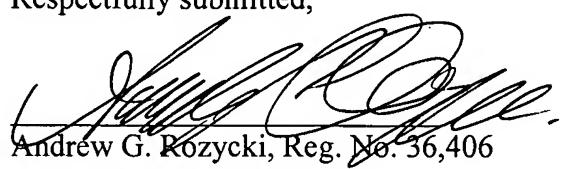
The claims are not unpatentable over the Krueger and Pyles references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

Conclusion:

In light of the above amendments and the accompanying remarks, it is believed that the application is now in condition for allowance, and prompt notification to that effect is earnestly solicited. The Examiner is invited to contact the undersigned to discuss the application on the merits if it is believed that such discussion would expedite the prosecution.

Respectfully submitted,

Dated: Oct 24, 2005


Andrew G. Rozycki, Reg. No. 36,406
Attorney for Applicants
Cardinal Health, Inc.
7000 Cardinal Place
Dublin, Ohio 43017
Tel. (614) 757-7413
Fax (614) 757-2243